PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr OLMESARTAN
Olmesartan Medoxomil Tablets USP

Read this carefully before you start taking **OLMESARTAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **OLMESARTAN**.

Serious Warnings and Precautions

OLMESARTAN should not be used during pregnancy. Taking OLMESARTAN during pregnancy can cause harm and even death to your baby. If you discover that you are pregnant while taking OLMESARTAN, stop the medication as soon as possible and contact your doctor.

What is OLMESARTAN used for?

OLMESARTAN is an angiotensin receptor blocker (ARB) used to lower blood pressure in adults and children above 6 years old.

High blood pressure increases the workload of the heart and arteries. If this condition continues for a long time, damage to the blood vessels of the brain, heart, and kidneys can occur, and may eventually result in a stroke, heart or kidney failure. High blood pressure also increases the risk of heart attacks. Reducing your blood pressure decreases your risk of developing these illnesses.

How does OLMESARTAN work?

OLMESARTAN contains olmesartan medoxomil which is a drug that prevents the hormone in your body that causes the blood vessels to constrict. OLMESARTAN lowers blood pressure by relaxing your blood vessels.

OLMESARTAN does not cure your high blood pressure. It helps to control it. Therefore, it is important to continue taking OLMESARTAN regularly even if you feel fine.

What are the ingredients in OLMESARTAN?

Medicinal ingredients: Olmesartan medoxomil

Non-medicinal ingredients: Colloidal anhydrous silica, hydroxypropylcellulose, hypromellose, lactose monohydrate, low-substituted hydroxypropylcellulose, macrogols 400, magnesium stearate, microcrystalline cellulose, stearic acid, talc and titanium dioxide.

OLMESARTAN comes in the following dosage forms:

Film-coated Tablets: 20 mg (white, round shaped) and 40 mg (white, oval shaped).

Do not use OLMESARTAN if you:

- are allergic to olmesartan medoxomil or to any of the other ingredients of OLMESARTAN.
- have experienced an allergic reaction with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ARB (You can recognize an ARB because its medicinal ingredient ends in "-SARTAN"). Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- are pregnant or intend to become pregnant. If this is the case, talk to your doctor as soon as possible. Taking OLMESARTAN during pregnancy can cause harm and even death to your baby.
- are breastfeeding. It is possible that OLMESARTAN passes into breast milk.
- have diabetes or kidney disease and are already taking a medicine that contains aliskiren (such as Rasilez), used to lower high blood pressure.

OLMESARTAN is not recommended for use in children below the age of 6 years.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OLMESARTAN. Talk about any health conditions or problems you may have, including if you:

- have experienced an allergic reaction to any drug used to lower blood pressure.
- have a narrow heart valve or arteries.
- had a heart attack or have heart or blood vessel disease.
- had a stroke or have a condition that affects the blood supply to the brain.
- have liver or kidney disease.
- have blocked bile ducts.
- have diabetes.
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- are on a low-salt diet.
- are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of "water pill" that makes your body keep potassium).
- are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure.
- are taking an angiotensin converting enzyme inhibitor (ACE inhibitors). You can recognize ACE Inhibitors because their medicinal ingredient ends in "**-PRIL**".
- are less than 18 years old or the drug is for your child.

Other warnings you should know about:

OLMESARTAN can prevent the normal growth of your baby's kidneys and skull if you take the drug during the second and third trimester. Your doctor may recommend an ultrasound.

OLMESARTAN can cause severe chronic diarrhea with substantial weight loss (sprue-like enteropathy). It can take months to years for symptoms to develop.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to OLMESARTAN. Dizziness, lightheadedness, or fainting can occur when you take the drug for the first time and when your dosage is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with OLMESARTAN:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of "water pill").
- Blood pressure lowering drugs, including diuretics ("water pills"), aliskiren-containing products (e.g. Rasilez), or angiotensin converting enzyme inhibitors (ACE Inhibitors).
- Diuretics
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib (COX-2 Inhibitor).

How to take OLMESARTAN

- OLMESARTAN may be taken with or without food.
- Take exactly as directed by your Doctor. Do NOT take more of it than prescribed.

Usual dose:

For adult patients:

- 20 mg tablet once daily.
- Can be increased to 40 mg once daily by your doctor if your blood pressure is not well controlled after two weeks of treatment.

For pediatric patients age (6 to 16 years old):

Weight between 20 kg to less than 35 kg:

- 10 mg once daily.
- Can be increased to 20 mg once daily by the doctor if blood pressure is not well controlled after two weeks of treatment.

Weight of 35 kg or more:

- 20 mg once daily.
- Can be increased to 40 mg once daily if blood pressure is not well controlled after two weeks of treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much OLMESARTAN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double dose.

What are possible side effects from using OLMESARTAN?
These are not all the possible side effects you may feel when taking OLMESARTAN. If you experience any side effects not listed here, contact your doctor.
Any medicine may have unintended or undesirable effects, so-called side effects.

Side effects may include:

- Back pain
- Decreased appetite
- Dizziness and headache
- Gastrointestinal problems
  - Constipation
  - Diarrhea
  - Nausea
  - Upset stomach
  - Vomiting
- Joint pain
- Muscle cramps, spasms and pain
- Rash, red itchy patches on skin
- Restlessness and weakness
- Upper respiratory infection
  - Congested and runny nose
  - Cough
  - Sore throat

OLMESARTAN can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Low Blood Pressure: dizziness, fainting, lightheadedness.	✓		
Bronchitis: shortness of breath, weakness, high fever, coughing, fatigue, wheezing or whistling sound when breathing.		✓	
Hematuria (blood in urine): pink, red or very dark urine.		✓	
UNCOMMON			
Ear Disorder (Vertigo): a sense of dizziness, spinning.		✓	
Tachycardia (abnormally fast	✓		

heartbeat): dizziness, light headedness, shortness of breath, racing heart.			
Hyperuricaemia (Increased levels of uric acid in the blood): swelling and redness in the joints.	✓		
Chest Pain: Pressure or tightness in your chest	✓		
Edema: unusual swelling of the arms, hands, legs, feet and ankles.	✓		
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		✓	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
RARE			
Acute Kidney Failure: decrease or absence of urine, generalized swelling, weakness, shortness of breath, or irregular heartbeats, loss of appetite, lethargy and fatigue.			✓
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Rhabdomyolysis (breakdown of damaged muscles): muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		✓	
Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell.		✓	
UNKNOWN			
Sprue-like enteropathy: severe chronic diarrhea with substantial weight loss.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
The tablets should be stored at 15-30°C.
Keep out of sight and reach of children and pets.

If you want more information about OLMESARTAN:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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